REMARKS

Reconsideration and withdrawal of the rejections of this application and consideration and entry of this paper are respectfully requested in view of the amendment, remarks and attachments herewith, which place the application in condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1, 4-7, 11-13, 45, 47-49 are pending. Claims 1, 4-7, 11-13 are amended, and new claims 47-49 added, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is submitted that these claims are patentably distinct from the documents cited by the Examiner, and that these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments to the claims and the remarks made herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but rather the amendments and remarks are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Support for the amended recitations in the claims is found throughout the specification and from the pending claims.

II. THE OBJECTION TO THE SPECIFICATION IS OVERCOME

The specification is objected to for allegedly incorporating essential material by reference. The objection is traversed.

It is initially and respectfully noted that the specification has been amended to correct an inadvertent typographical error in the recitation of U.S. Application Serial No. 09/152,775. New matter has not been added as a search in the U.S. Patent and Trademark Office website indicates that this serial number shares the same title as that recited in the specification. Further, the specification has been amended without prejudice, without admission, without surrender of subject matter and without any intention of creating any estoppel as to equivalents, to remove reference to Appendix I.

Although Applicants respectfully disagree that essential material has been incorporated herein by reference, in order to expedite prosecution, Applicants have amended the instant specification to include the material incorporated by reference from U.S. application Ser. No. 09/346,905, now U.S. Patent No. 6,239,112; U.S. application Ser. No. 09/112,690, now U.S. Patent No. 5,958,888; and U.S. application Ser. No. 09/152,775, now U.S. Patent No. 6,174,540 and EP 99 402 482.6. The material incorporated by reference in the instant application can be found at col. 8, line 46 to col. 9, line 13, of U.S. Patent No. 6,239,112; col. 6, lines 14-31, of U.S. Patent No. 5,958,888 and col. 11, line 41 to col. 12 line 64, of U.S. Patent No. 6,174,540 Although, Applicants disagree that essential material has been incorporated herein by reference, it should be noted that even if the material is held to be essential material, it is proper to incorporate essential material by reference if it is a U.S. patent, a U.S. patent application, or a pending U.S. application (see MPEP §608.01(p)). Provided herewith is a clean copy (see Exhibit 1) and a marked up copy (see Exhibit 2) of the substitute specification and substitute Figures 1-16 (see Exhibit 3) submitted under 37 CFR 1.125(a) to facilitate the Examiner's review of changes made to the specification. With regard to EP 99 402 482.6, a Declaration is provided by the undersigned that states that the amendment to the specification to incorporate EP 99 402 482.6 does not constitute new matter. Furthermore the undersigned hereby affirms and confirms that no new subject matter is added by the attached substitute specification and substitute Figures 1-16.

Consequently, the objection to the specification should be reconsidered and withdrawn; and, such relief is respectfully requested.

III. THE REJECTIONS UNDER §112, SECOND PARAGRAPH, ARE OVERCOME

Claims 1, 4-7, 11-13 and 45 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. The rejection is traversed.

The amended recitations to the claims, and the addition of new claims 47 and 48, made without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents, have rendered the instant rejection moot.

Consequently, the Section 112, second paragraph, rejection should be reconsidered and withdrawn; and, such relief is respectfully requested.

IV. THE REJECTIONS UNDER §103 ARE OVERCOME

Claims 1, 4-7, 11-13 and 45 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 5,698,584 to Black et al., and U.S. Patent Nos. 5,981,576 and 6,020,343 to Belley et al. taken with U.S. Patent No. 6,017,520 to Synodis et al., U.S. Patent No. 5,880,076 to Vermeer et al., U.S. Patent No. 5,266,304 to Baffelli et al. and U.S. Patent No. 5,958,458 to Norling et al. The rejection is respectfully traversed. None of the numerous documents (indeed, seven (7) documents relied upon in a single rejection based on alleged obviousness), either alone or in combination, teach, suggest or disclose the present invention.

Applicants' invention is directed to, *inter alia*, a pharmaceutical or veterinary paste formulation comprising an effective amount of a therapeutic agent; fumed silica; a viscosity modifier comprised of two or more functional groups for forming hydrogen bonds on the surface of the fumed silica; and a carrier. None of the seven documents relied upon in the Office Action suggest, teach or motivate a skilled artisan to practice the instant invention.

The Examiner is respectfully reminded of the case law; namely, that there must be some prior art teaching which would have provided the necessary incentive or motivation for modifying the reference teachings. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowitz*, 27 U.S.P.Q. 2d 1063 (BOPAI 1993). Further, "obvious to try" is not the standard under 35 U.S.C. §103. *In re Fine,* 5 U.S.P.Q. 2d 1596, 1599 (Fed. Cir. 1988). And, as stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification." Also, the Examiner is respectfully reminded that for the Section 103 rejection to be proper, both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicants' disclosure. *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

One of the unique features of the instant invention is the utilization of a viscosity modifier comprised of two or more functional groups for forming hydrogen bonds on the surface of the fumed silica. Specifically, the functional groups of the viscosity modifier form hydrogen bonds with the silanols on the surface of the fumed silica particles. Applicants have unexpectedly discovered that:

> The addition of the viscosity modifier provides for a paste formulation which contains less fumed silica than the amount normally used in a conventional paste. The inventive formulation

> allows for all the air that is introduced into the formulation by the fumed silica to escape when the viscosity is low. The viscosity modifier is then added to bring the viscosity of the paste to the desired level without the introduction of more air into the final product. While not wishing to be bound by theory, it is believed that because of their functional groups, the viscosity modifiers act as crosslinkers and extend the three-dimensional network formed by the interaction of the silica and the hydrophobic carrier. The viscosity modifiers also extend the crosslinking density in the formulation.

(Specification, at 27).

None of the cited documents disclose, suggest or motivate a skilled artisan to, *inter alia*, use such a viscosity modifier. Indeed, neither U.S. Patent No. 5,698,584, nor 5,981,576, nor U.S. Patent 6,020,343 even recite "fumed silica," let alone suggest a viscosity modifier comprised of two or more functional groups for forming hydrogen bonds on the surface of the fumed silica. Further, none of the other documents relied upon in the Office Action, i.e., U.S. Patent No. 6,017,520, U.S. Patent No. 5,880,076, U.S. Patent No. 5,266,304 and U.S. Patent No. 5,958,458, disclose, suggest or teach a viscosity modifier comprised of two or more functional groups for forming hydrogen bonds on the surface of the fumed silica. Consequently, the inevitable conclusion is that the Examiner has picked and chosen portions of disparate references in order to formulate the obviousness rejection; and, that is not permissible under U.S. patent law.

Moreover, in addition to not suggesting the addition of fumed silica, U.S. Patent No. 5,694,584 does not even provide for paste compositions. While U.S. Patent No. 5,694,584 generally describes various formulations for COX-2 inhibitors, none of these formulations is a paste composition. The patent merely describes oily suspension in column 26, second paragraph, wherein thickening agents, such as beeswax, paraffin or cetyl alcohol, are added to the suspension; the patent is silent as to whether there is a paste. U.S. Patent Nos. 5,981,576 and 6,020,343 suffer from similar deficiencies.

Likewise, U.S. Patent Nos. 5,880,076 and 5,266,304 do not describe paste formulations. U.S. Patent No. 5,880,076 discloses detergent or personal compositions which are not edible. The most which he said is that compositions for oral hygiene product are described. The patent is merely a fastidious recitation of all ingredients which may be suitable for such a compositions and, thus, clearly does not suggest the inventive paste formulations. U.S. Patent No. 5,266,304

discloses a dental care or tooth cleaning paste comprising a very substantial amount at least 40% of perlite. A thickening agent, such as aerosil, can be present. Clearly such a formulation is not edible. Thus, these prior patents do not suggest the inventive pastes for these additional reasons.

Indeed, it cannot even be argued that any of the documents "inherently" teaches or discloses, *inter alia*, a pharmaceutical or veterinary paste formulation comprised of, *inter alia*, a viscosity modifier comprised of two or more functional groups for forming hydrogen bonds on the surface of the fumed silica. It is not enough for one to contend (or for the Examiner to imply) that the compounds or methods in the relied-upon documents "inherently" speak to the instantly claimed invention. It is, in fact, impermissible to "speculate" that the relied-upon documents "inherently" speak to the instantly claimed invention. Speculation is not enough. *See Rapoport* v. *Dement*, 59 U.S.P.Q.2d 1215 (Fed. Cir. 2001). The documents must disclose or suggest the properties for inherency to attach. According to *In re Rijckaert*, 9 F.3d 1531, 1957 (Fed. Cir. 1993), "such a retrospective view of inherency is not a substitute for some teaching or suggestion supporting an obviousness rejection." The Federal Circuit is clear that "'inherency...may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient [to establish inherency].'" *Continental Can Company v. Monsanto Company*, 948 F.2d 1264, 1269 (Fed. Cir. 1991), *citing to In re Oelrich*, 666 F.2d 578, 581-582 (C.C.P.A. 1981). Indeed, "before a reference can be found to disclose a feature by virtue of its inherency, one of ordinary skill in the art viewing the reference must understand that the unmentioned feature at issue is *necessarily* present in the reference." *SGS-Thomson Microelectronics, Inc. v. International Rectifier Corporation*, 31 F.3d 1177 (Fed. Cir. 1994) (emphasis in original).

Applying the law to the instant facts, none of the documents cited in the Office Action inherently teach, disclose or suggest Applicants' invention. That is, none of the documents inherently teach, disclose or suggest, *inter alia*, a pharmaceutical or veterinary paste formulation comprised of, *inter alia*, a viscosity modifier comprised of two or more functional groups for forming hydrogen bonds on the surface of the fumed silica. Thus, inherency cannot attach.

Consequently, reconsideration and withdrawal of the rejections are believed to be in order and such action is respectfully requested.

REQUEST FOR INTERVIEW

If any issue remains as an impediment to allowance, an interview with the Examiner and his SPE is respectfully requested, prior to issuance of any paper other than a Notice of Allowance; and, the Examiner is respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

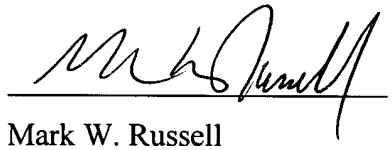
See MPEP 408

CONCLUSION

In view of the remarks and amendments herewith and those of record, the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance, or an interview at a very early date with a view to placing the application in condition for allowance, are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP

By: 

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

1. (Amended) A pharmaceutical or veterinary paste formulation comprising:

(a) an effective amount of a therapeutic agent;

(b) fumed silica;

(c) a viscosity modifier comprised of two or more functional groups for forming hydrogen bonds on the surface of the fumed silica; and

(d) a carrier[;

(e) optionally, an absorbent; and

(f) optionally, a colorant, stabilizer, surfactant, or preservative].

4. (Amended) The [paste] pharmaceutical or veterinary paste formulation according to claim 1, comprising:

(a) a therapeutic agent selected from the group consisting of avermectins, milbemycins, nordulisporic acid and its derivatives, estrogens, progestins, androgens, substituted pyridyl methyl derivatives, phenylpyrazoles, COX-2 inhibitors [or] and a proton pump inhibitor[.];

(b) fumed silica;

(c) a viscosity modifier comprised of two or more functional groups for forming hydrogen bonds on the surface of the fumed silica;

(d) an absorbent;

(e) a colorant; and

(f) a carrier [which is] selected from the group consisting of triacetin, a monoglyceride, a diglyceride, [or] and a triglyceride.

5. (Amended) The pharmaceutical or veterinary paste formulation according to claim 4, wherein the viscosity modifier is selected from the group consisting of PEG 200, PEG 300, PEG 400, PEG 600, monoethanolamine, triethanolamine, glycerol, propylene glycol, polyoxyethylene sorbiton monoleate, [or] and poloxamers; the absorbent is selected from the group consisting of magnesium carbonate, calcium carbonate, starch, [or] and cellulose and its derivatives; and the colorant is selected from the group consisting of titanium dioxide, dye [or] and lake.

6. (Amended) The pharmaceutical or veterinary paste formulation according to claim 1, which, based upon total weight of composition, comprises:

(a) about 0.01 to about 50% of a therapeutic agent;

(b) about 0.02 to about 20% fumed silica;

(c) about 0.01% to about 20% of a viscosity modifier comprised of two or more functional groups for forming hydrogen bonds on the surface of the fumed silica;

(d) 0% to about 30% of an absorbent;

(e) 0% to about 20% of a colorant; and

(f) [Q.S.] a carrier.

7. (Amended) The pharmaceutical or veterinary paste formulation according to claim 4, which based upon total weight of the composition, comprises:

(a) about 0.01 to about 50% of a therapeutic agent;

(b) about 1% to about 6.5% fumed silica;

(c) about 0.05% to about 5% of a viscosity modifier comprised of two or more functional groups for forming hydrogen bonds on the surface of the fumed silica;

(d) about 1% to about 10% of an absorbent;

(e) 0.01% to about 10% of a colorant; and

(f) [Q.S.] a carrier.

11. (Amended) The pharmaceutical or veterinary paste formulation according to claim 5, wherein the therapeutic agent is a COX-2 inhibitor.

12. (Amended) The pharmaceutical or veterinary paste formulation according to claim 11, wherein the COX-2 inhibitor is 3-(cyclopropylmethoxy)-5,5-dimethyl-4-(4-methylsulfonyl)phenyl)-5H-furan-2-one or 3-(cyclopropylethoxy)-5,5-dimethyl-4-(4-methylsulfonyl)phenyl)-5H-furan-2-one or pharmaceutically acceptable salts or hydrates of these compounds.

13. (Amended) The pharmaceutical or veterinary paste formulation according to claim 12, wherein the COX-2 inhibitor is the polymorphic B form of 3-(cyclopropylmethoxy)-4-[4-(methylsulfonyl)phenyl-5,5-dimethyl]-5H-furan-2-one.

PATENT
454313-2330

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s)	:	Jun CHEN
U.S. Serial No.	:	09/504,741
Filing Date	:	February 16, 2000
For	:	**IMPROVED PASTE FORMULATIONS**
Examiner	:	Michael V. Meller
Art Unit		1651

745 Fifth Avenue
New York, NY 10151

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Date of Deposit: December 14, 2001

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" Service under 37 CFR 1.10 on the date indicated above and is addressed to the Honorable Commissioner of Patents and Trademarks, Washington, DC 20231.

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DECLARATION

Assistant Commissioner for Patents
Washington, D.C. 20231

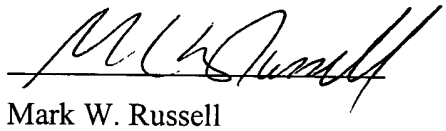
Dear Sir:

I, Mark W. Russell, Registration Number 37,514, Attorney of Record for the above-referenced application, declare that the amendment to the specification of the above referenced application constitutes no new matter. Rather, the amendment to the specification consists of the same material previously incorporated by reference to foreign patent EP 99 402 482.6 and the EP

99 402 482.6 application and Figures were attached at Appendix I with the above-identified application as filed.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP

By: 

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